UNIVERSITI KUALA LUMPUR
ROYAL COLLEGE OF MEDICINE PERAK

FINAL EXAMINATION
MARCH 2026 SEMESTER

COURSE CODE	:	RCB31103
COURSE NAME	:	PHARMACEUTICAL PACKAGING
PROGRAMME NAME	:	BACHELOR IN PHARMACEUTICAL TECHNOLOGY (HONOURS)
DATE	:	22 JUNE 2026
TIME	:	2.30 PM – 4.30 PM
DURATION	:	2 HOURS

INSTRUCTIONS TO CANDIDATES

1. Please read CAREFULLY the instructions given in the question paper.
2. This question paper has information printed on both sides of the paper.
3. This question paper consists of TWO (2) sections; Section A and Section B.
4. Answer ALL questions in Section A. For Section B, answer THREE (3) questions WITH AT LEAST ONE (1) question from question 3 or question 4.
5. Please write your answers on the OMR answer script and answer booklet provided.
6. Answer all questions in English language ONLY.

THERE ARE 10 PAGES OF QUESTIONS, EXCLUDING THIS PAGE.

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SECTION A (Total: 40 marks)

I) MULTIPLE CHOICE QUESTIONS (20 marks)

INSTRUCTION: Answer ALL questions.

Use the OMR sheet provided.

1. Packaging protects the product from the following external factors.
   - I. Light
   - II. Moisture
   - III. Mechanical damage
   - IV. Chemical interactions

   A. I only
   B. II only
   C. III and IV
   D. I, II, and III
   E. I, III, and IV

2. Identify the main reason for repackaging drug products.

   A. To supply the drug products required for a short period of time.
   B To prevent wastage of drug products.
   C. To minimise external contamination.
   D. To reduce cost.
   E. To comply with standard dispensing practice.

3. Select the drug products that can be repacked during dispensing.
   - I. Capsules
   - II. Tablets
   - III. Powdered drugs for reconstitution
   - IV. Eye drops

   A. I only
   B. II only
   C. I and II
   D. I, II, and III
   E. I, III, and IV

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4. Identify a suitable primary packaging format for tablets.

A. Blister packs
B. Sachets
C. Ampoules
D. Vials
E. Tubes

5. Identify the component that contributes 15-20% of the total weight of the blister pack.

A. Forming film
B. Lidding material
C. Heat seal coating
D. Printing ink
E. Adhesive layer

6. Identify the **CORRECT** USP glass classification that can be used to pack aqueous injectables of pH less than 7.

I. Type I
II. Type II
III. Type III
IV. Type NP

A. I only
B. II only
C. I and II
D. I, II, and III
E. I, III, and IV

7. This packaging has a resealable strip at top and is made from low-density polyethylene film.

A. Plastic pouches
B. Aluminium pouches
C. Blister packaging
D. Aluminium foil
E. Glass bottles

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8. **"This is the oldest and most widely used class of adhesive and starch is classified under it."**

Identify the class of adhesive described above.

A. Hot-melt adhesive
B. Solvent-based adhesive
C. Water-based adhesive
D. Solvent-less adhesive
E. Pressure-sensitive adhesive

9. What is the primary concern when handling printed packaging materials during sampling?

A. Preventing the mixing up of different materials.
B. Checking for proper colour calibration of prints.
C. Ensuring the materials are aesthetically pleasing.
D. Verifying the quantity of materials received.
E. Checking the physical appearance of the materials.

10. Which department is responsible for finding vendors for required products and services in the pharmaceutical industry?

A. Human resource department
B. Research and development department
C. Purchase department
D. Production department
E. Quality control department

11. A pharmaceutical company is auditing a new supplier. They want to ensure the supplier can show clear records of every step in their manufacturing process. Which aspect of supplier evaluation does this relate to most directly?

A. Obtaining latest production facilities and equipment.
B. Demonstration of traceability.
C. Analytical and stability evaluation.
D. Consistency of material quality.
E. Compliance with ICH Q7 and general quality system.

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12. A customer is considering reducing in-house testing of material. What is the basis for deciding the level of quality assessment, and why is this approach recommended for 'critical' raw materials?

A. Based on production efficiency; to streamline manufacturing.
B. Based on sales volume; to ensure high turnover.
C. Based on marketing strategy; to increase brand loyalty.
D. Based on risk assessment; to ensure adequate scrutiny for high-impact materials.
E. Based on human resource evaluation; to ensure adequate supply of skilled workers.

13. A customer is evaluating a supplier and considers using the supplier's own evaluation procedures for the manufacturer. Under what condition is this permissible?

A. Only if the supplier allows it.
B. Only if the material supplied is non-critical.
C. Only if the supplier is a close friend of the customer.
D. Only if the customer trusts the supplier implicitly without documentation.
E. Only if it is documented as part of the customer's supplier evaluation procedure.

14. **"The possibility of establishing a long-term business relationship with the supplier will be evaluated."**

Which criteria will determine the above statement in supplier selection and management process?

A. Supply chain security
B. Quality assessment
C. Supplier selection process
D. Due diligence
E. Ongoing monitoring and evaluation

15. What is the recommended way to express the strength of a pharmaceutical product?

A. Writing only the concentration per mL
B. Writing the total quantity per total unit volume
C. Using abbreviations only
D. Writing the molarity of the product
E. Writing the strength in percentage only

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16. Where should the dosage label ideally be placed on pharmaceutical packaging?

A. Anywhere on the package
B. At the bottom of the package
C. On a specific surface area near the generic name and strength
D. On the back only
E. Inside the package

17. Which of the following best explains why writing "25 mg/5 mL" is preferred over "5 mg/mL" on pharmaceutical labels?

A. It ensures compliance with international color-coding standards.
B. It simplifies interpretation by matching the stated strength with the actual dosage unit used.
C. It increases the stability of the medication.
D. It eliminates the need for dosage labels.
E. It reduces the manufacturing cost of the drug.

18. How can similar pharmaceutical names be differentiated to avoid confusion?

A. Removing parts of the name
B. Highlighting sections with capital letters
C. Writing the names in abbreviations
D. Writing names in lowercase
E. Using smaller font sizes

19. Why is aluminum foil used in the thermoforming process after the pockets are filled with tablets or capsules?

A. To increase the flexibility of the packaging material.
B. To reduce the size of the blister packs.
C. To transport the tablets to the hopper.
D. To form the initial pockets for the tablets.
E. To seal the filled pockets and provide a surface for printing code information.

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20. Why are downstream processes such as labeling, cartoning, and case packing for solid dosage forms similar to those used in liquid packaging lines?

A. Solid and liquid products have identical chemical properties.

B. Same filling equipment is always used for both forms.

C. Packaging operations after filling follow standardized processes regardless of dosage form.

D. Solid dosage forms do not require labeling.

E. Blister packaging replaces all downstream operations.

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II) SHORT ANSWER QUESTIONS (20 marks)

INSTRUCTION: Answer ALL questions in the answer booklet provided.

Each question carries TWO (2) marks.

1. Describe a pressure-sensitive adhesive.

2. State the retention period for primary packaging materials.

3. List **TWO (2)** steps during the visual checking on the number of pallets according to ISO 2859 -1.

4. State **ONE (1)** cGMP objective for final medicinal products.

5. Define risk in a supplier selection process.

6. List **TWO (2)** areas that can be evaluated in the quality systems of a supplier.

7. State **TWO (2)** factors that should be considered in the structural design of pharmaceutical packaging.

8. State **TWO (2)** information that are recorded on line-stoppage sheet.

9. List **TWO (2)** attributes that are recorded by the operator at the start of the blister packaging lines.

10. What are the two types of blister packs?

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SECTION B: MODIFIED ESSAY QUESTIONS (Total: 60 marks)

INSTRUCTION: This section consists of FOUR (4) questions.
You are required to answer THREE (3) questions in the answer booklet provided.
Question 1 and 2 are COMPULSORY.
Answer EITHER Question 3 OR 4.

Question 1

(a) A pharmaceutical company is developing a new tablet formulation and preparing for regulatory submission. Describe the types of stability studies to be conducted during the developmental phase and explain how they differ from those required for the registration dossier phase.

(10 marks)

(b)



Explain the packaging issue occurring in the figure above.

(10 marks)

Question 2

(a) A liquid pharmaceutical product with a pH of 5 containing phosphate buffer, stored in glass bottles, failed during stability study. The following observations were made:

i. The pH of the product increased to 8.

ii. Glass flakes were detected in the solution.

iii. Aluminium oxide was detected in the product upon analysis.

Explain the probable interactions between the product and the glass bottle for each observation.

(10 marks)

(b) During a stability study, an oxygen-sensitive product packaged in a low-density polyethylene (LDPE) bottle has oxidised. As the product formulator, evaluate the possible causes of this issue and propose suitable strategies to overcome it.

(10 marks).

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Question 3

(a) Modern pharmaceutical packaging has evolved from a passive containment system into a safety system, data carrier, and digital platform. Justify this statement.

(10 marks)

(b) As a formulator, you are required to suggest an appropriate packaging material for a new vaccine. Identify a suitable type of USP glass and justify your choice.

(10 marks)

Question 4

(a) Explain the benefits of automated packaging inspection technology in terms of regulatory compliance and minimising human error in pharmaceuticals.

(10 marks)

(b) Explain and illustrate the peelable foil and child-resistance foil designs used in lidding materials.

(10 marks)

END OF EXAMINATION PAPER

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